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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1656

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,731

Applicant(s)

SMIT, JOHN

Examiner

David J. Steadman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2006 and 19 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6,9,11 and 12 is/are rejected.
- 7) ☒ Claim(s) 2,5 and 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Status of the Application

- [1] A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/19/2006 has been entered.
- [2] Claims 1-6 and 9-12 are pending in the application.
- [3] Applicant's amendment to the claims, filed on 5/10/2006, has been entered. This listing of the claims replaces all prior versions and listings of the claims.
- [4] Applicant's arguments filed on 5/10/2006 have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.
- [5] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, Second Paragraph

- [6] The rejection of claim 13 under 35 U.S.C. 112, second paragraph, is withdrawn in view of the amendment to cancel the claim.

Claim Rejections - 35 USC § 112, First Paragraph

[7] The new matter rejection of claims 1-6 and 9-12 under 35 U.S.C. 112, first paragraph, is withdrawn in view of the amendment to claims 1 and 9 to limit the S-layer protein to a protein comprising SEQ ID NO:5. MPEP § 2163 states that “there is no *in haec verba* requirement” for newly added claim limitations, only that “newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure” (MPEP 8th Ed., October 2005 Revision, p. 2100-175). According to the same section of the MPEP, “[t]he fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc.*, 935 F.2d at 156364, 19 USPQ2d at 1117.” While the claim limitation of “fragment comprises the C-terminal 120 amino acids” of SEQ ID NO:5 may not have *in haec verba* support in the specification, the limitation nonetheless has support at p. 9, lines 19-23 of the specification, which states (in relevant part), that the fusion protein may have the C-terminal region of *C. crescentus* S-layer beginning at amino acid 907. Amino acids 907 to 1026 of SEQ ID NO:5 are the C-terminal 120 amino acids of SEQ ID NO:5. Thus, it is the examiner’s position that the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed.

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[8] The written description rejection of claims 1-6 and 9-12 under 35 U.S.C. 112, first paragraph, is withdrawn in view of the amendment to claims 1 and 9 to limit the *C. crescentus* S-layer protein to comprising the amino acid sequence of SEQ ID NO:5.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

[9] Claims 1, 3-4, 6, 9, and 11-12 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bingle et al. (*J Bacteriol* 179:601-611, 1997; cited as reference AC in the IDS filed on 5/24/2001) as evidenced by Walker et al. (*J Bacteriol* 174:1783-1792, 1992; cited as reference AO in the IDS filed on 10/21/2002) and Landen in "Methods in Enzymology," Volume XLVII, 1997, pp. 145-149.

Claims 1 and 3-4, and 6 are drawn to a method of cleaving an insoluble fusion protein at a cleavage site and claims 9 and 11-12 are drawn to a method of producing a protein heterologous to *C. crescentus*.

The reference of Bingle et al. teaches *C. crescentus* S-layer proteins comprising an internal linker peptide having the sequence -Thr-Asp-Pro-Ser- inserted at positions

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229, 250, or 510 (p. 604, Figure 2). Bingle et al. teaches that linker-peptide insertions at positions 229 and 250 yielded protein that remained anchored to the cell surface (p. 605, right column, middle), wherein the protein was removed from the cell surface by low-pH extraction according to a method disclosed by Walker et al. (*supra*). See p. 603, right column, bottom and p. 605, right column, middle.

The references of Walker et al. and Landen are cited in accordance with MPEP 2131.01 as showing that a characteristic not disclosed in the reference of Bingle et al. is inherent – in this case, that the conditions used for low-pH extraction of the linker-peptide inserted protein would have inherently resulted in cleavage of the protein at the Asp-Pro bond of the linker. Walker et al. teaches a method of low-pH extraction of *C. crescentus* S-layer protein using a buffer at pH 2 and incubating at a temperature of 65°C (p. 1784, right column, top). Landen teaches that an Asp-Pro bond is labile at low pH and is hydrolyzed under acidic conditions of pH 2.5 and at elevated temperature (pp. 145-146).

This anticipates claims 1, 3-4, 6, 9, and 11-12 as written.

The following examiner comments are provided to clarify the record. Although Bingle et al. does not expressly disclose cleavage of the linker-peptide insertion proteins at the Asp-Pro of the inserted linker, it is the examiner's position that this is an inherent result of the low-pH extraction method as disclosed by Walker et al. for releasing the linker-peptide insertion protein from the cell surface. By virtue of exposing the linker-peptide insertion protein at pH 2 at 65°C, the protein would have been cleaved at the Asp-Pro bond. Regarding the limitation that requires the "second component" to be

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"heterologous" to *C. crescentus*, by virtue of inserting the linker into the *C. crescentus* polypeptide, the N-terminal portion of the *C. crescentus* polypeptide, with the addition of at least a Thr that is not normally present in the native *C. crescentus* polypeptide, the examiner considers the N-terminal portion of the linker-peptide insertion protein to be "heterologous" to *C. crescentus*.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

Conclusion

[10] Status of the claims:

Claims 1-6 and 9-12 are pending.

Claims 1, 3-4, 6, 9, and 11-12 are rejected.

Claims 2, 5, and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David J. Steadman, Ph.D.
Primary Examiner
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